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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/025,282	BLEYER ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-60,62,66 and 67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-60, 62, 66 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11-04-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Applicants' amendment filed on 11-03-2008 has been entered.
3. Status of claims. Claims 54-60, 62, 66 and 67 are pending. Claims 66 and 67 have been added by Applicants' amendment filed on 11-03-2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Therefore, claims 54-60, 62, 66 and 67 are currently being examined to which the following grounds of rejection are applicable.

Response to arguments

Rejections maintained in response to Applicant arguments or amendments

Claim Rejections - 35 USC § 103

Claims 54-60 and 62 remain rejected and new claims 66 and 67 are rejected under 35 USC § 103 as being unpatentable over Badylak et al., (US Patent No. 6,099,567, effective priority filing date, 10 December 1996) in view of Stinson et al., (US 2004/0111149 A1, Date of filing August 1, 1997).

In addition to the issues of rejection discussed in the previous office action of 07-02-2008, new claim 66 raises rejection issues in relation to the collagenous biomaterial being in a lyophilized form and new claim 67, a product-by-process claim, raises rejection issues in so far as limiting the localization of the radiopaque marker between a first layer and a second layer of a multilayer.

In so far as the formulation of the implantable biomaterial in a lyophilized form (e.g., a freeze-dry procedure), Badylak et al., at column 3, lines 20-37, describes that the submucosa tissue is grinded in a frozen or freeze-dried state. Moreover, Badylak contemplates the use of powder forms of stomach submucosa prepared by pulverizing stomach submucosal tissue under liquid nitrogen to produce particles which are then lyophilized overnight (col. 3, liens 39-45)**(Current claim 66).**

In relation to the location of the radiopaque marker localized between the first and second layer of the multilayer biomedical device, Badylak et al., discloses that the stomach submucosa composition can be folded or partially everted to provide multiple layers for gripping, for example, with spiked washers or staples (col. 5. lines 50-55) or "multiple strips/pieces of stomach submucosa can be overlapped and compressed, under conditions allowing dehydration of the tissue, to fuse the strips/pieces of the stomach submucosal tissue into a unitary multi-laminate construct (col. 6, lines 4-7). Stinson complements the teachings of Badylak by disclosing bioabsorbable radiopaque markers for use on an implantable biomaterial such as endoprosthesis, e.g., stents and grafts, in order to improve radiopacity and visualize the passage and placement of the endoprosthesis (p. 1, paragraphs [0002]-[0007]). Moreover, Stinson et al., discloses that bioabsorbable-radiopaque markers should be of sufficient thickness to provide sufficient radiopacity for imaging and may have one or more hollow, cavity, or porous portions wherein radiopaque material may be disposed (p. 2, paragraph [0021]). Additionally, Stinson teaches that is preferable to use small amounts of the radiopaque substances in the implant by incorporating the discrete bioabsorbable-radiopaque marker rather than to load the entire implant with the radiopaque material (p.2, paragraph 20). Note the

radiopaque collagenous biomaterial device of claim 67 is claimed as a product-by-process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product). Furthermore, since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for

believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Therefore, in view of the benefits of using bioabsorbable radiopaque markers in grafts to enhance radiopacity and visualize the placement of the implantable graft, as taught by Stinson, it would have been *prima facie* obvious for one of ordinary skill in the art to incorporate a radiopaque marker in the implantable multilayer device taught by Badylak. A person of ordinary skill would have had a good reason to dispose the radiopaque marker between any of the strips of the multilayer implantable device in an attempt to improve radiopacity for imaging, as a person with ordinary skill has good reason to pursue the known options within his grasp. The use of bioabsorbable collagenous materials as well as radiopaque elements was routine or well-established in the art at the time of filing. Furthermore, the disclosure of the specification as-filed fails to provide any new elements in the product as claimed.

Response to Applicants' Arguments as they apply to rejection of claims 54-60, 62, 66 and 67 under 35 USC § 103

At pages 5 and 6 of the Remarks, Applicants essentially argue that Stinson explicitly states that "the markers of the invention can be segregated into types: threaded and discrete bioabsorbable markers." In addition, Applicants cite Stinson's Figures 5 and 11 allegedly providing support for the contention that Stinson's markers could be only

threaded or woven to the Badylak graft but not disposed in between layers of the graft material. Such is not persuasive.

Though Figure 5 discloses examples of threaded markers in a braided helical pattern on an implantable endoprosthesis (page 5, paragraph [0044]); page 7, paragraphs [0066] [0069], and Figure 11 illustrates discrete bioabsorbable-radiopaque markers made by forming small rings or coils of bioabsorbable-radiopaque, respectively, Stinson teaches alternative embodiments of bioabsorbable-radiopaque markers no looped (e.g., threaded or woven) one or more times to a filament For example, at page 8, paragraph [0081], Figure 9 discloses a bioabsorbable-radiopaque marker (e.g.,14) disposed in pores (e.g., 35) having the pores connected to a reservoir of radiopaque material that allows the radiopaque material disposed in the marker to exit from the marker. Indeed, in addition to the marker as a mono-filament, multi-filament, thread, ribbon and suture, Stinson discloses throughout the document markers including one or more hollow, cavity, porous, and combinations thereof wherein the radiopaque material is disposed (p.2, paragraph [0021];p. 3, paragraphs [0030][0031]). Thus the teaching of discrete bioabsorbable-radiopaque markers made by forming small rings or coils of bioabsorbable-radiopaque filament around features of the implantable endoprosthesis does not precluded the success of alternative embodiments drawn to disposed bioabsorbable-radiopaque markers in between layers of graft material.

Conclusion

Claims 54-60, 62, 66 and 67 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Michael Burkhart/

Primary Examiner, Art Unit 1633